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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/757,100      | 01/09/2001  | Brett P. Monia       | ISPH-0533           | 6913             |

7590

06/25/2003

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT

PAPER NUMBER

1635

18

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/757,100

Applicant(s)

MONIA ET AL.

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 45-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 45-55 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION*****Election/Restrictions***

In response to the rejections of record, Applicant has amended the claims to read on methods that utilize compounds targeted to multiple target regions within the target gene (SEQ ID NO: 1). A search of the full length target gene (SEQ ID NO: 1) is not effective to provide an adequate search of each of the individual regions within SEQ ID NO:1. To provide an adequate search for methods utilizing compounds targeted to each of the individual regions claimed, it would require a separate search of each of the claimed regions, based on the nucleotide sequence of each region. Therefore, pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the targeted regions listed in claim 45 are subject to restriction.

The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of individual nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application (see MPEP 803.04 and 2434).

Claim 45 specifically claims methods that utilized compounds targeted to 15 different nucleotide regions within SEQ ID NO: 1, which modulate the expression of focal adhesion kinase. Although the methods claimed utilize compounds that modulate expression of the same gene, the compounds targeted to each sequence region are considered to be unrelated, since each compound targeted to a sequence region claimed is structurally and functionally independent and distinct for the following reasons: each compound has a unique nucleotide sequence based on the sequence of

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the target region claimed, each compound targets a different and specific region of a nucleotide encoding FAK, and each compound, upon binding to FAK, functionally inhibits the expression of FAK to a varying degree (per applicants' Table in the specification). Since the compounds used in these methods are unrelated, the claimed methods are also not related, being directed to methods which use structurally distinct compounds. Furthermore, to adequately search the claimed methods it would require a separate search of each of the compounds targeted to each of the claimed regions. This search would be distinct, as it would require a separate search of each region, based on the nucleotide sequence of the target region. A search of more than one (1) of the nucleotide sequences of the target regions specified in the methods of claim 45 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the methods directed to these target region sequences. In view of the foregoing, one (1) nucleotide sequence (i.e. one target region) is considered to be a reasonable number of sequences to search for examination of the claimed methods. Accordingly, applicants are required to elect one (1) target region sequence from claim 45.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
June 23, 2003

  
KAREN LACOURCIERE  
PATENT EXAMINER